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The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

January 10, 2005

Division of Dockets Management
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

[Docket No. 2004D-0466] Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act; Availability
69 Federal Register 64962, November 9, 2004.

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following comments on the docket referenced above.

1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5900

The National Food Processors Association (NFPA) is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international Members. NFPA Members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers. In 2005, NFPA will become the **Food Products Association (FPA)**.

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NFPA supports the draft guidance that FDA has developed on structure-function claims for dietary supplements. NFPA particularly supports the approach that the Agency has taken, namely, to apply the substantiation standard of the Federal Trade Commission, that of "competent and reliable scientific evidence," to substantiation of structure-function claims on labels of dietary supplements. NFPA believes that substantiation based on competent and reliable scientific evidence should support health benefit statements expressed on the labels of food, including both dietary supplements and conventional foods. Substantiation based on competent and

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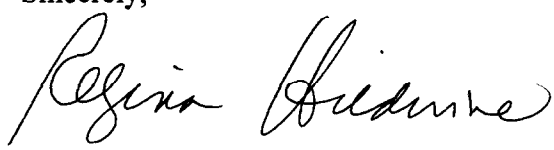
reliable scientific evidence would ensure that a label claim is both truthful and non-misleading.

NFPA believes that the FDA draft guidance will provide a clear path for marketers of dietary supplements to follow when assembling the information to support a claim. The elements of the draft guidance, including considerations for the meaning of the claim, the relationship of the evidence to the claim, and the quality and totality of the evidence, will lead responsible supplement marketers to state structure-function claims that reflect the supporting evidence, and that do not overstate the purported health effects of the supplement.

NFPA also believes that the draft guidance presents concepts that are useful in developing structure-function claims for conventional foods. NFPA intends to refer to FDA's draft guidance as it assists its Members that seek advice on expressing such claims. NFPA believes that FDA's draft guidance is consistent with the approach that NFPA recently adopted in its guidance for making structure-function claims for conventional foods. For the reference of the Agency, and for public availability on this docket, NFPA has attached a copy of its 2003 guidance "Making Structure-Function Claims for Food," to this comment.

Thank you for the opportunity to comment on this important issue.

Sincerely,



Regina Hildwine
Senior Director
Food Labeling and Standards

Attachment

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Suite 300
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NFPA Guidance

Making Structure-Function Claims for Food

This NFPA Guidance is intended to assist manufacturers of food products for which structure-function claims are made in food labeling or advertising. This Guidance addresses the food safety and claims substantiation principles applicable to foods for which structure-function claims are made under the governing provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This Guidance also integrates key principles derived from the body of antideception law, including the claims substantiation standards that have been developed under the Federal Trade Commission Act (FTC Act) and the comparable consumer protection laws adopted by the 50 states. Under the basic antideception requirements of the FD&C Act, FTC Act, and the comparable state laws, structure-function claims for foods, like other consumer product claims, must be stated accurately, and be supported by evidence providing a reasonable basis for the specific claim that is made. Structure-function claims that are false, unsubstantiated, or otherwise deceptive are prohibited under both federal and state antideception law. This NFPA Guidance applies to all food products, except for products marketed as "dietary supplements" within the meaning of section 201(ff) of the FD&C Act, to which distinct legal standards apply.

Introduction

Structure-function claims are statements about the way that a food, or a substance in a food, may affect or maintain the structure or function of the body. Food, by its very nature, functions in the natural systems of the body to support growth and health. Virtually all foods help to ameliorate hunger and thirst, and thus have important effects on how the body functions. Scientific evidence establishes that food provides substances vital to the functioning of the body's systems, providing energy through macronutrients, supplying essential vitamins, minerals, and other micronutrients, providing moisture and hydration, or supplying other physiologically active components. Since it is arguable that all foods have a role in affecting the structure or function of the body, it follows that virtually all foods could express a structure-function claim.

In recent years, scientific investigations have clarified the role of food in supporting human health. As the relationships between food and human health become better understood, science has shown that a wide variety of food components, beyond those recognized as physiologically essential, participate in the body's natural mechanisms to sustain life and health. Foods provide these characteristics whether their physiologically active components are naturally occurring or added to the basic food,

or whether the food is specially formulated to deliver a specific effect through the use of novel ingredients. Advances in science have improved understanding of the important ways that food contributes health benefits and have supported opportunities to communicate those benefits publicly.

Statutory Standards for Structure-Function Claims

Food is recognized by the FD&C Act to affect the structure and function of the body.[1] Accurate, substantiated claims communicating the role of food in supporting the structures and functions of the body are authorized under the original provisions of the FD&C Act adopted in 1938.

The term "structure-function claim," derived from section 201(g)(1)(C) of the FD&C Act, is commonly understood to encompass both express and implied claims communicating the benefits of food and food components in promoting and maintaining the health of the normal structures and functions of the body, and the documented mechanisms by which these benefits are maintained.[2] Structure-function claims are permitted provided they are stated in a truthful and non-misleading manner and are substantiated by appropriate scientific evidence. These considerations apply regardless of whether such claims appear in food labeling matter regulated under the FD&C Act, or advertising, Internet, or other promotional matter subject to the anti-deception requirements of the FTC Act and the overlapping consumer protection statutes in the 50 states.[3]

The FTC Act prohibits "unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices."[4] "Unfair or deceptive acts or practices" is defined to include "the dissemination or the causing to be disseminated of any false advertisement...."[5] Dissemination encompasses distribution "by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food...."[6]

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[1] Under section 201(g)(1)(C) of the FD&C Act, an article that is "intended...to affect the structure or any function of the body of man" is subject to regulation as a "drug," except in the case that the article qualifies as a "food" under the Act. This exclusion of "food" from the drug definition recognizes that food, by its very nature, affects the structure and function of the body. Further, section 201(f) of the FD&C Act defines "food" to mean "articles used for food or drink for man..., chewing gum, and articles used for components" of any such food. 21 U.S.C. 321(f). This definition of "food" has been interpreted to encompass articles "consumed primarily for taste, aroma, or nutritive value," including conventional foods. Nutrilab v. Schweiker, 713 F.2d 335, 338 (7th Cir. 1983).

[2] 21 U.S.C. 321(g)(1)(C). ("[t]he term 'drug' means ... articles (other than food) intended to affect the structure or any function of the body of man or other animals...").

[3] See, e.g., Federal Trade Commission Act sections 12 & 15, 15 U.S.C. section 52 & 55; (http://www.ftc.gov/bcp/guides/ad3subst.htm), (http://www.ftc.gov/bcp/policystmt/ad-decept.htm).

[4] 15 U.S.C. 45(a)(1).

[5] 15 U.S.C. 52(b).

[6] 15 U.S.C. 52(a)(1).

Structure-function claims made to market food products constitute commercial speech. Provided these claims are stated in a manner that is accurate, not misleading, and fully substantiated by evidence providing a reasonable basis for the claim, such claims are protected from government regulation that would restrict the free expression of these claims under the First Amendment.[7]

As reflected in the 1998 submission made to FDA by the Staff of the FTC Bureau of Consumer Protection, the framework that has been established under the FTC Act to prohibit false advertising claims and unfair practices provides a reliable standard for structure-function claims appearing in food labeling. This framework is set out in the FTC's Deception Policy Statement[8] and Substantiation Policy Statement,[9, 10] and is distilled into two fundamental legal principles: (1) advertising must be truthful and not misleading; and (2) advertisers must have substantiation for all objective claims before the claims are disseminated.[11]

The FTC guidance explained that, "Under FTC law, identifying the claim conveyed by an ad is the first step in any determination of what level of support is required to substantiate that claim. The FTC will look at the overall impression of the ad and consider statements in the context of all elements of the ad."[12] For claims about the efficacy of food products, the FTC typically holds advertisers to a substantiation standard referred to in numerous FTC orders as "competent and reliable scientific evidence" and defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."[13]

The FTC substantiation policy has been interpreted to require the following factors to be considered in assessing the adequacy of the evidence to support the specific claim that is made: (1) the type of product advertised; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field believe is necessary.[14] The FTC policy noted that while claims typically

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[7] See Daniel E. Troy, Advertising: Not "Low Value" Speech, 16 Yale J. on Reg. 85, 92 (1999).
[8] See Cliffdale Associates, Inc., 103 F.T.C. 110, 176 (1984), reprinting as appendix letter dated Oct. 14, 1983, from the Commission to The Honorable John D. Dingell, Chairman, Committee on Energy and Commerce, U.S. House of Representatives ("Deception Policy Statement").
[9] FTC Policy Statement on Advertising Substantiation, 48 Fed. Reg. 10471 (1984), reprinted in Thompson Medical Co., 104 F.T.C. 648, 839 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987)("Substantiation Policy Statement").
[10] F.T.C., Dietary Supplements: An Advertising Guide for Industry 3 (1998)("FTC Advertising Guide"), available at http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm.
[11] Id.
[12] Id.
[13] Id. at 9; see, e.g., Thompson Medical Co., 104 F.T.C. 648 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987)(requiring two adequate and well-controlled clinical studies to substantiate certain drug claims).
[14] Id. at 8.

present anti-deception issues, in those cases where a product is promoted in a manner that "causes, or is likely to cause, substantial injury to consumers, which is not reasonably avoidable by consumers themselves and is not outweighed by the countervailing benefits to consumers," the claim would also be prohibited.[15]

Key Principles: Safety of Food Product Formulation and Expression of Structure-Function Claims

Foods for which structure-function claims are made remain subject to the range of food safety requirements ordinarily applied to food under the FD&C Act. Food ingredients that contribute to the structure-function benefits of food are prohibited unless the ingredient is used in accordance with an FDA food additive approval,[16] a "prior sanction,"[17] or established as "Generally Recognized as Safe" (GRAS).[18] These safety standards apply in a product-specific manner and require manufacturers to establish that food is safe under the conditions of its intended use. In evaluating novel conditions of use of food ingredients and formulations, an important aspect of a safety determination considers the probable consumption level of the ingredients and the cumulative effect of new contributions to the existing exposure levels occurring through the human diet.[19]

Under relevant statutory standards, the health benefits of foods promoted through the use of structure-function claims, as well as the safety of the food and its ingredients, must be substantiated based on sound scientific evidence. The following sets out key principles for assessing the evidence supporting the safety and health benefits of food. Each principle includes hypothetical examples to illustrate its application to food product development and claims.

Key Principle 1: Safety of Food Product Formulation

Foods are safe and functional ingredients must be established as safe under the intended conditions of use in which the food will be consumed. This precept is fundamental to the development of food products for which claims are intended to emphasize the benefits to the structure or function of the body.

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[15] Id. at note 7.
[16] 21 U.S.C. 348.
[17] 21 U.S.C. 321(s)(4)(excluding from "food additive" definition "any substance used in accordance with a sanction or approval granted prior to [September 6, 1958] pursuant to the [FD&C Act], Poultry Products Inspection Act, . . . or the Meat Inspection Act....").
[18] 21 U.S.C. 321(s)(excluding from the "food additive" definition "substances that are "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common used in food) to be safe under the conditions of its intended use....").
[19] See 21 C.F.R. 170.30.

For the safety of a food ingredient to be established, the conditions under which the food product containing the ingredient will be consumed as food must be evaluated. These conditions constitute the conditions of intended use for a food ingredient, and require safety to be established for food products on a case-by-case basis to ensure the intended use is either established as GRAS or authorized under a food additive regulation. While the established patterns of use of an ingredient in other food products sometimes can provide important evidence of GRAS status, these may not be sufficient to establish safety for ingredient uses in foods consumed under conditions where the populations exposed or levels of exposure are different. This means that an ingredient that is established as GRAS for one type of use or level of consumption is not necessarily safe for another use or level of consumption. Special care is necessary when evaluating the safety of novel ingredients or novel uses of ingredients for which there is no prior established history of use in the food. However, when a structure-function claim is made on an unmodified whole food, the food is presumed to be safe (e.g., broccoli, chocolate, coffee, milk, orange juice, spinach, tea, tomatoes).

> *Example: A food manufacturer contemplates adding caffeine to a non-carbonated sports drink beverage, with the expectation of making structure-function claims for the beverage related to athletic performance. Under FDA regulations, caffeine is affirmed as GRAS in food "when used in cola-type beverages in accordance with good manufacturing practice" at levels not exceeding 0.02% of the formulation.*[20] *The manufacturer's intended use of caffeine in the sports drink beverage is not encompassed within the scope of the FDA regulation. Before proceeding to include caffeine in the sports drink formulation, the manufacturer would be required to establish the safety of the intended caffeine use under the FD&C Act (e.g., establish GRAS status under the intended conditions of use).*

Food companies interested in employing novel conditions of use for food ingredients should establish the safety of these conditions in accordance with FDA guidelines governing toxicological principles [21] for evaluations of ingredients as GRAS[22] or food additives.[23] The intended use of the ingredient must be evaluated, concomitant with information on anticipated levels of consumption. In particular, food formulations that may facilitate *ad libitum* versus intended levels of consumption of an ingredient (e.g., in beverage form) must address both possibilities in a safety assessment.

> *Example: A food processor considers formulation of a blended juice drink with the addition of lycopene, an antioxidant that occurs*

[20] 21 CFR 182.1180.
[21] See http://www.cfsan.fda.gov/~redbook/red-toca.html.
[22] 21 CFR Parts 182 and 184.
[23] 21 CFR Part 172.

naturally in tomatoes and tomato products. Considering that lycopene has an established history of human consumption as a natural component of foods commonly consumed as part of an ordinary diet, it is likely that the safety of foods (e.g., blended juice drink) specially formulated to supply lycopene at levels consistent with established intake levels can be established. To establish safety, at a minimum, the food processor would need to consult the scientific literature concerning lycopene safety, including with respect to any safety issues associated with both high consumption levels of tomato products naturally containing lycopene, and isolated forms of lycopene relevant to the blended juice drink formulation. Considering that tomatoes and tomato products are plentiful in the food supply, and frequently consumed by many, the processor must consider the safety and efficacy effects of further consumption when adding lycopene to foods that are not sources of the food component.[24]

In the case of ingredients that have a history of use in dietary supplements, but no historical use in a category of conventional food products for which a new use is contemplated, safety evaluations should account for any differences in the safety standards that may apply in the dietary supplement category which would not apply equally to conventional foods.

In the case of ingredients that have had historical uses, such as botanical ingredients, GRAS determinations for modern food applications should take into consideration the scope and nature of such historical use. Appropriate consideration should be given to the comparative conditions of use (e.g., sporadic short-term use vs. constant consumption), patterns and levels of exposure, and chemical forms (e.g., extraction or concentration vs. natural form from plant parts) of the functional ingredients.

Example: The research and development department of a food company is considering development of a beverage product that includes an infusion of the herb Echinacea. The product is intended to be marketed seasonally to the general population, based on the purported function of Echinacea to support immune function. During the course of product development, the research team would conduct a safety assessment of the herb, taking into account long-term and short-term courses of intake. Following the safety evaluation, the food company researchers conclude that the ingredient would be safe to use in food for short-term consumption, based on studies of the herbal ingredient in dietary supplements that examined its safety and

[24] This product presents additional regulatory considerations. The lycopene imparts color, yet is not *per se* listed as an approved color additive, possibly necessitating further regulatory considerations. Care must be taken with any label statements highlighting the lycopene in the food. Label statements that disclose the quantity per serving of substances without a Daily Value are accommodated in regulations, while statements that characterize the level may be unauthorized nutrient content claims.

utility as a remedy for wintertime maladies. Because of the success of the product in its first market season, the marketing department of the food company urged the researchers to develop a product that could be available year-round, in the form of a tea marketed to the general population. The researchers must reexamine their safety evaluation, and ascertain whether there is sufficient evidence of safety over a long-term course of consumption to justify development of the year-round beverage.

Example: A food processor is considering adding an herbal ingredient, which has a purported health benefit, to a cereal grain product. The food product considered for development would use the whole leaf of the herb, not an infusion, in a food product that would be marketed to adults for daily consumption. The supplier of the ingredient assures the food processor the ingredient would be safe to use in the cereal grain product because it has been used for centuries to impart the health benefit. The supplier does not present the processor with data or other information to support this assertion. The food processor would need to investigate both the history of safe use of the ingredient and its purported health benefits. The food processor, in researching the matter, discovers that the ingredient had been used since the Middle Ages and in Chinese medicine to treat a specific disease condition. Information in the literature of herbal lore indicated the ingredient should be prepared as an infusion or water extract of particular concentration, not the whole leaf of the plant, and administered by the practitioner to a patient over a treatment course of specific length. The herbal manuals urged the infusion not be used to treat children. There were no adequate, well-controlled modern clinical studies that had been conducted to evaluate the safety of the herb, whole leaf or its extractives by means of consumption as food. Examination of the toxicology literature on the safety of the herb or its extractives showed five reports of hives in children exposed to the herbal infusion. In view of the marketing and distribution plan, children reasonably could be exposed to this product. Based on information obtained in the investigation on history of use, form of product (whole leaf vs. infusion), temporal recommendations, population limitations, the supervised administration of the infusion, and any effects of the food matrix, the food processor would need to resolve whether there are too many unanswered questions or challenging issues regarding the safety of the herb, and decide whether or not to formulate the cereal grain product with this ingredient.

Key Principle 2: Expression of Structure-Function Claims

A claim that communicates the effect of a food or food component on the structure or function of the body must be substantiated by sound scientific evidence that provides a reasonable basis for the specific claim made by the manufacturer, and considers both the express and implied messages conveyed by the claim. Food processors should exercise care in tailoring the language of claims to ensure that the meaning conveyed is accurate and fully supported by the substantiating evidence on which the claim relies. Broadly stated or vague claims which may over-generalize the conclusions that may be drawn from the scientific evidence, or exaggerate health benefits, should be avoided. This standard applies to claims disseminated by means of food labeling, advertising, Internet web sites, or through other promotional vehicles. Food companies may wish to consider the use of panels of outside scientific experts, when appropriate, in the development of structure-function claims.

The structure-function benefits of a food product that either are communicated expressly or implied are required to be substantiated by evidence providing a reasonable basis for the claim, considering the specific language of the claim and the conditions of food consumption.

Claims must be based on substantiation from the peer-reviewed scientific literature, proprietary research, or other authoritative sources. Most structure-function claims do not require consideration of consumption patterns since they focus on issues unrelated to consumption level (e.g., "Calcium helps build strong bones and teeth."). Accordingly, provided the amount of the nutrient or functional component in the food is physiologically significant, efficacy is not an issue. For example, in the case of a nutrient with an established Daily Value (DV), a significant amount would be the minimum level that qualifies for at least a "good source" nutrient content claim (between 10 percent and 19 percent Daily Value contribution per reference amount customarily consumed and per serving). However, depending upon the anticipated structure-function claim, the required amount might need to be minimum level that qualifies for an excellent source claim ((20 percent Daily Value or more contribution per reference amount customarily consumed and per serving).

When a DV has not been established, study would be needed to determine the amount of the component that is significant and the relevance of the food component in the context of overall dietary patterns. Furthermore, analyses are needed on a case-by-case basis to decide whether there is enough of the functional component in the food to support the structure-function claim presented, particularly when the food matrix is different from those examined in published scientific studies. In these cases, a substantiation of the claim based on scientific data is essential. The specific language of the structure-function claim is critically important since that determines the amount of substantiation required (e.g., specified language, caveats, disclaimers, that qualify the meaning of the claim).

Example: A food processor contemplates adding a calcium compound to orange juice. Several calcium compounds are listed as GRAS or affirmed GRAS in FDA regulations for comparable uses. Because of the structure-function benefits of adequate calcium intake in building and maintaining healthy bones and teeth, the food processor wishes to include a label claim noting the role of calcium in building strong bones. In the process of considering this nutrient addition, the food processor must calculate the likely additional calcium consumption across population groups that would result from the consumption of the commonly ingested food product. Information on increased calcium consumption would then be balanced against information on likely frequency of consumption and the tolerable upper intake level of calcium intake, currently set at 2,500 mg per day by the Food and Nutrition Board. The food processor might decide to fortify orange juice at 20% Daily Value per serving, sufficient to qualify for a "high" claim.[25]

Example: A food processor wishes to formulate a dilute juice beverage with an herbal extract purported to help support the circulatory system with a label claim that notes this functional effect. The food processor would need to conduct the necessary safety investigation for the herbal ingredient, examining the scientific literature for distinctions in effects between use of the plant parts and use of extractives of the plant parts. The investigation revealed, among other facts, that small quantities of an infusion, or aqueous extract, of a particular part of the plant were prescribed for use by herbalists in the Middle Ages to improve "flowe of the bloode" in the body, over a long course of treatment. Chemical analysis of the extract suggested that the component estimated to convey the physiological effect was similar in structure to salicylates, the active component in over-the-counter drugs such as aspirin. The researchers concluded that a physiological effect was imparted by the extract at low levels of consumption, but that there was little scientific evidence of safe use in food consumed freely. Given these factors, the product developer would need to decide whether it would be appropriate to develop the product as a food.

Representations made for the functional effects of foods or food components must be truthful and non-misleading. To ensure they are truthful and non-misleading, such

[25] This food product presents additional regulatory challenges. Calcium fortified orange juice must be formulated and labeled in a manner consistent with the standards of identity for orange juice (21 CFR part 146) and requirements for standardized foods that make nutrient content claims (21 CFR 130.10). In this food, the calcium compound may have an effect on the pH of the finished food, a technical factor that may need to be taken into consideration with respect to the processing and handling of the finished product.

statements used in labeling, advertising, the Internet, or other promotional material must be substantiated by sound scientific evidence that relates to the statements expressed and implied.

If the statement implies that the whole food provides the benefit, then substantiation must address the whole food, as opposed to research conducted solely on an ingredient isolated from the finished product. As noted previously, food manufacturers must consider whether the amount of functional ingredient is significant with respect to the implied or stated benefit claim.

For structure-function claims concerning well established nutritional benefits of nutrients or foods consumed at ordinary levels, the evidence providing a reasonable basis for the claim can sometimes be documented from scientific texts, consensus reports, or other secondary sources which authoritatively characterize the relevant body of scientific evidence. For example, the claim, "calcium helps build strong teeth and bones" may be easily substantiated based on a history of widely accepted research into the essentiality of the mineral and the fact that a DV is established for the nutrient, as well as a thorough understanding of the mechanism of action of the mineral in the body's skeletal and dental systems.

Where the substantiation for claims is not well established, review of the body of relevant scientific studies is necessary to ensure claims are framed in a manner that is accurate and fully substantiated by the evidence. For example, substantiation of the claim, "Dietary patterns rich in calcium help to maintain blood pressure within normal range," may require consideration of the body of relevant research findings through a review of the original scientific studies. Substantiation of such claims will depend on the nature of scientific investigations and the quality of the studies, including the controls imposed on blood pressure variables other than dietary calcium and the consistency of the research database. If sufficient studies exist, it may be possible to substantiate such a claim through secondary sources. In both circumstances, scientific studies that support a potential claim must be considered in the context of the surrounding body of scientific evidence to clarify the significance of the substantiating scientific evidence. The claim itself should provide sufficient material qualifying information so that consumers can understand any potential limitations of the science related to claimed health benefits.

> *Example: A food manufacturer considers adding ginger, a GRAS food ingredient, to apple juice for its purported positive effect on digestion. In addition, the manufacturer considers making a structure-function claim regarding ginger and digestion. A review of the literature indicates that ginger has long been discussed in herbal folklore as beneficial to digestion. In considering development of this food product, the manufacturer will need to examine the use of ginger as a food ingredient beyond traditional use as a food flavor. The food manufacturer would need to consult the scientific literature to assess the level of addition of ginger necessary to deliver the intended*

benefit to the structure and function of the body, and the effects of acute versus chronic ingestion of ginger.

Example: A food manufacturer contemplates making a structure-function claim on a blueberry product about the function of anthocyanin, a phenolic component found in blueberries (and other fruits), to promote healthy vision. The food company researchers would need to study the scientific literature on anthocyanin to affirm whether the research supports the purported physiological effect. The scientific literature substantiates that blueberries are one of the major dietary contributors of this phenolic compound, and experimental studies describe the role of anthocyanin in blueberries in promoting healthy vision. The food manufacturer must consider the quality of the research and if there were any safety effects of increased consumption of blueberries themselves before proceeding with the development of a structure-function claim regarding healthy vision from anthocyanin in blueberries. Thus, the specific language of the structure-function claim determines the type of scientific substantiation and specificity required. For example—

- *Blueberries help support normal vision.*
- *Blueberries help keep your vision youthful.*
- *Anthocyanins in blueberries help support normal vision.*
- *Anthocyanins in blueberries may help promote healthy vision.*

Finally, for structure-function claims, consideration should be given to the health of the general population as well as to particularly vulnerable subpopulations. If such use presents potential health risks of concern, food processors should adopt food labeling and marketing strategies that provide appropriate public health protection.

Example: A food for special dietary use, formulated with folic acid and other nutrients needed by women of childbearing years might reasonably be consumed by elderly women. Food label claims describe the usefulness of these nutrients for women preparing for pregnancy, including, for folic acid, "adequate levels of folic acid in your blood may help support healthy neurological development of your baby following conception." Elevated consumption levels of folic acid and, as a result, serum folate levels, may mask symptoms of vitamin B_{12} deficiency, especially among the elderly. A processor of the food in question may need to consider changes in consumption patterns. Then, additional label statements might be needed to advise any elderly consumers concerning this potential health risk.

In summary, advances in science have improved understanding of the important ways that food contributes health benefits and have supported opportunities to communicate those benefits publicly. Structure-function claims that communicate

these benefits must follow legal and regulatory standards. Safety of the food component must be evaluated under the intended conditions of use. Both expressed and implied claims must be substantiated based on sound scientific evidence and presented to consumers such that any limitations in the science are understood. These principles and guidance apply to claims made in food labeling, advertising, Internet web sites, or communicated through other promotional vehicles.

November 2003